US007811533B2

# (12) United States Patent
Bechini

(10) Patent No.: US 7,811,533 B2
(45) Date of Patent: *Oct. 12, 2010

(54) **UNIT FOR STERILISING AND DEPYROGENATING CONTAINERS**

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( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/794,656**

(22) PCT Filed: **Jan. 11, 2006**

(86) PCT No.: **PCT/IB2006/000029**

§ 371 (c)(1),
(2), (4) Date: **Mar. 3, 2008**

(87) PCT Pub. No.: **WO2006/075227**

PCT Pub. Date: **Jul. 20, 2006**

(65) **Prior Publication Data**

US 2008/0260609 A1 Oct. 23, 2008

(30) **Foreign Application Priority Data**

Jan. 12, 2005 (IT) ..... BO2005A0011

(51) **Int. Cl.**
*A61L 2/04* (2006.01)

(52) **U.S. Cl.** ..... **422/308**; 414/150

(58) **Field of Classification Search** ..... 414/150; 422/308

See application file for complete search history.

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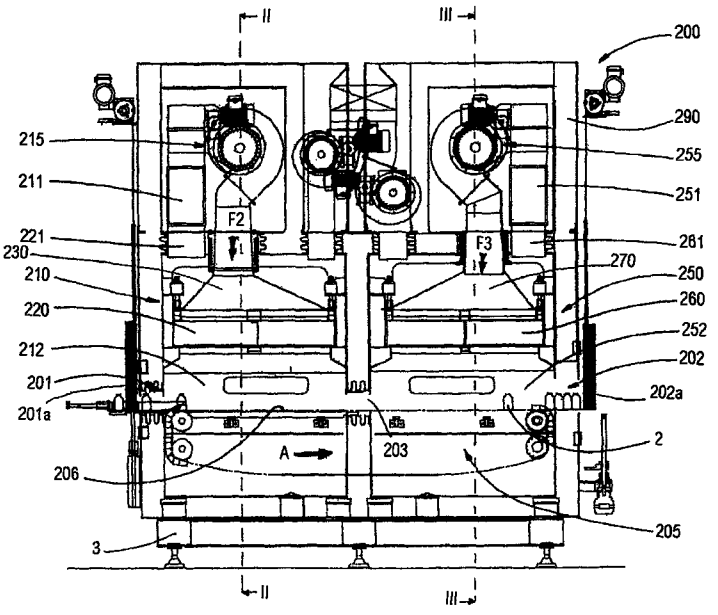
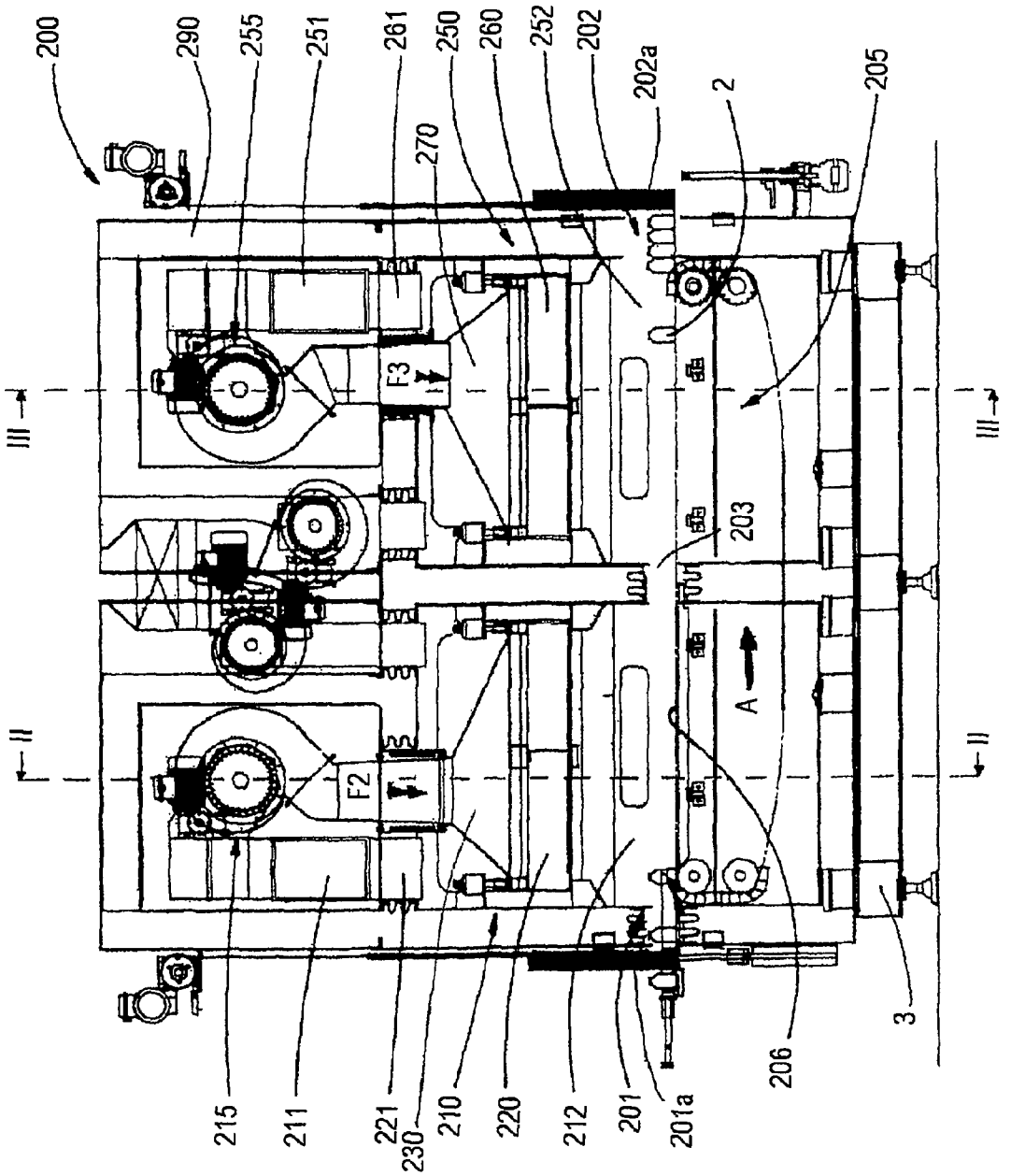
(57) **ABSTRACT**

A unit for sterilizing and depyrogenating containers of the type including a conveying device suitable for receiving a plurality of containers through at least an inlet and supplying the containers in a set direction to a corresponding outlet of the unit. The unit has a sterilizing/depyrogenating unit defined by at least two sterilizing modules arranged consecutively in said direction and communicating through an intermediate passage and affected by the conveying device. The sterilizing modules are activatable independently of one another according to alternative operating modes for hot and/or cooling sterilizing the containers.

**6 Claims, 2 Drawing Sheets**

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290
255
251
261
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260
252
202
202a
2
205
270
III
F3
203
A
II
F2
215
211
221
230
210
220
212
201
201a
206
3

Fig. 1

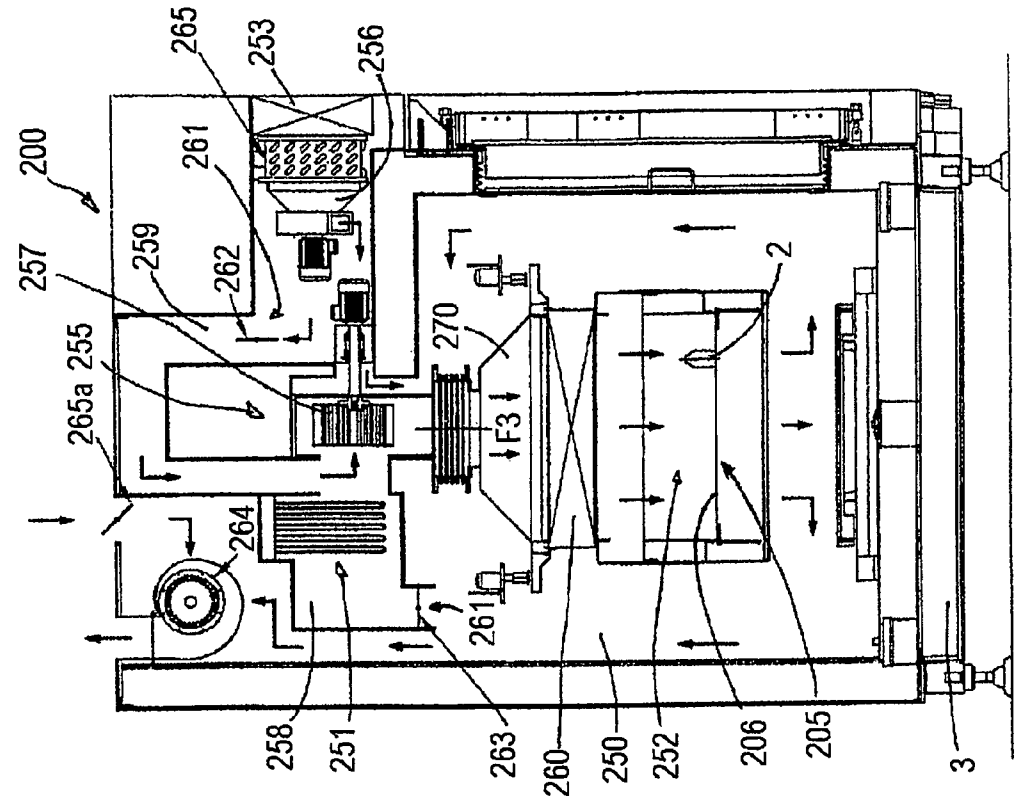
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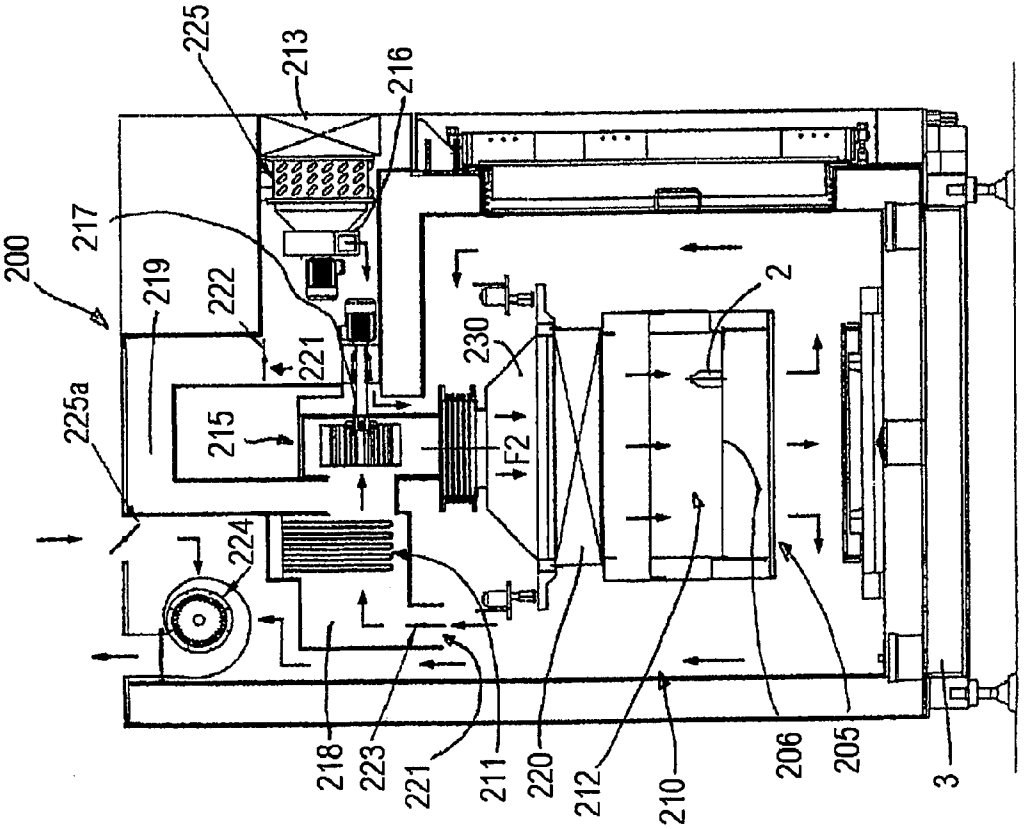
Fig. 3


200
225
213
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217
219
222
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230
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225a
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212
210
206
205
3

Fig. 2

# UNIT FOR STERILISING AND DEPYROGENATING CONTAINERS

This application is the U.S. national phase of International Application No. PCT/IB2006/000029 filed 11 Jan. 2006 which designated the U.S. and claims priority to IT B02005A000011 filed 12 Jan. 2005, the entire contents of each of which are hereby incorporated by reference.

The present invention forms a part of the technical field relating to the packaging of products in a protected environment.

In particular, the invention relates to a containers sterilising and depyrogenating unit, mainly bottles suitable for being filled with pharmaceutical products, in liquid or powder form, to which the following disclosure makes specific reference without thereby losing in generality.

The object of the invention is to realize a sterilising and depyrogenating unit, the use of which enables optimal, rapid and efficient sterilising and depyrogenating of bottles by selecting at will the four possible alternative modes of combined hot-cold, hot-hot, cold-hot or cold-hot sterilising.

According to the present invention a unit for sterilising and depyrogenating containers is realized of the type comprising conveying means suitable for receiving a plurality of said containers through at least an inlet and supplying the containers in a set direction to a corresponding outlet of the unit; the unit being characterised in that it comprises a sterilising/depyrogenating arrangement defined by at least two sterilising modules arranged consecutively in said direction and communicating through an intermediate passage, and affected by said conveying device; said sterilising modules being activatable independently of one another according to alternative hot sterilising and/or cooling operating modes of the containers.

The features of the invention as they will appear from the claims are pointed out in the following detailed disclosure made with reference to the attached drawings, in which:

FIG. **1** illustrates schematically a side view, partially sectioned and with parts removed for clarity, of an embodiment of a unit for sterilising and depyrogenating containers according to the invention in subject; and

FIGS. **2** and **3** are two cross-section views respectively according to II-II and according to III-III of the sterilising unit in FIG. **1**, in two respective different functional operating positions.

With reference to FIG. **1**, **200** indicates overall a unit for sterilising and depyrogenating containers **2**, in particular empty bottles **2** suitable for being subsequently filled with liquid or powder material used in the pharmaceutical field.

The unit **200** is defined by a two-stage sterilising arrangement **200** provided with a single base **3**, which arrangement **200** comprises a pair of sterilising modules, respectively a first module **210** and a second module **250**, arranged consecutively and communicating together by means of an intermediate passage **203**.

These modules **210** and **250** of the unit **200** of the present invention are advantageously activatable independently of one another according to operating modes hot and/or cold sterilising the bottles **2**.

In other words, by suitably activating in relation to one another the modules **210** and **250**, as will be better explained below, it is possible to achieve optimal, rapid and safe sterilising/depyrogenating of the bottles **2** with the following four combined alternative operating modes: hot-cold, hot-hot, cold-cold or lastly, cold-hot.



The entire arrangement **200** is completely enclosed inside a single insulated covering structure **290**, intended for preventing significant heat losses to the external environment.

The arrangement **200** furthermore comprises a belt conveyor **205**, arranged in the lower part thereof between a loading inlet **201**, made in the first sterilising module **210**, and an unloading outlet **202**, made in the second sterilising module **250**.

Still according to what has been illustrated in the attached FIG. **1**, the conveyor **205** is intended for supporting an ordered plurality of bottles **2** on an upper branch **206** thereof to convey the bottles **2** in a horizontal advancing direction A inside and through, in sequence, the first module **210** and the second module **250**.

The loading inlet **201** and the unloading outlet **202** are provided with corresponding shutters **201***a*, **202***a* that are vertically movable suitable for enabling the opening and closing thereof for the passage of bottles **2** respectively entering and exiting the unit **200**.

In the first sterilising module **210** a sterilising chamber **212** is obtained, the lower part of which is affected by the aforementioned conveyor **205**.

According to what has been better illustrated in FIG. **1**, in the upper part of the first module **210** by means of suitable conduits and separating baffles an air flow F**2** is realized that is intended for affecting the bottles **2** according to the modes subsequently disclosed to identify two different alternatively selectable heating or cooling paths of the bottles **2**.

This flow F**2** flows above the conveyor **205** in a hood **230** below which a filtering element **220** is provided that is defined by a HEPA filter the class which is suitable for obtaining the desired degree of air purity.

In the first module **210** a generating device **215** for generating the aforementioned air flow F**2** is also provided.

It is important to note that the first **210** and second **250** sterilising modules have a substantially identical structure: thus, similarly to the first module **210**, also the second module **250** is suitable for defining a corresponding identical sterilising chamber **252**, affected in the lower part thereof by the aforementioned conveyor **205**, and is provided with an identical flow generating device **255** for generating an air flow F**3** traversing and flowing into a hood **270**, with an identical filtering element **260** or HEPA filter.

Therefore, in the embodiment illustrated in FIG. **1**, the two modules **210** and **250** are arranged specularly, so that the aforementioned intermediate passage **203** consists of corresponding openings realized in the modules **210**, **250** made to match each other.

Further openings made at the opposite ends of the modules **210**, **250** respectively form the aforementioned loading inlet **201** and unloading outlet **202** of the present sterilising arrangement **200**.

As already mentioned above, both the first module **210** and the second module **250** may operate as both hot or cold sterilisers, as can now be observed respectively in FIG. **2** and in FIG. **3**.

According to what has been illustrated in the first part of the aforementioned Figures, FIG. **2**, with which for simplicity and clarity it is intended to disclose the first module **210** suitable for operating in hot sterilizing mode, in the first sterilising module **210** the sterilizing chamber **212** is obtained that is affected in the lower part thereof by the aforementioned conveyor **205**.

In the upper part of the first module **210** a path is realized for an air flow F**3** intended for affecting the bottles **2** accord-

ing to the modes disclosed below, and comprising two alternatively selectable heating **218** and cooling **219** branches of the bottles **2**.

This path leads above the conveyor **205** into the hood **230** below which the aforementioned filtering element **220** or HPA filter are fixed.

Inside the heating branch **218** a heating element **211** is located that is substantially defined by a coil resistor intended for heating the aforementioned air flow F**2** up to a preset sterilising/depyrogenating temperature of the bottles **2**.

In the first module **210** the aforementioned generating device **215** for generating the aforementioned air flow F**2** is also provided.

The generating device **215** comprises an inlet fan **216** arranged at an air intake **213** and suitable for sucking air from the external environment, and a main fan **217**, arranged above the aforementioned hood **230** and suitable for conveying to the bottles **2** the air flow F**2** through the HEPA filter **220** in a substantially laminar mode.

The first sterilising module **210** further comprises a refrigerating arrangement **225** that is selectively activatable and intended for rapidly cooling the air flow entering the aforementioned first module **210**, when the latter is arranged in the cooling operating mode.

At the inlet of the aforementioned heating **218** and cooling **219** branches, flow-commuting members **221** are provided.

These substantially comprise a pair of butterfly commutators **222**, **223**, that are commutable in push-pull mode between respective open and closed positions to connect or disconnect corresponding heating **218** and cooling **219** branches from the air flow F**2** path.

In the upper part of the first module **210** an evacuation fan **224** is provided that is intended for conveying part of the circulating air flow to the external environment.

With this fan **224** a mixing valve **225***a* is associated, that is arrangeable according to different opening degrees, intended for mixing in suitable proportions air coming from the external environment with the part of the air flow that enters the evacuation fan **224**, to lower the temperature of the exiting air.

Similarly to what has been illustrated in FIG. **2**, now referring to FIG. **3**, with which for simplicity and clarity it is intended to disclose the second module **250** suitable for operating in cold mode, the second module **250** defines the sterilising chamber **252**, affected in the lower part thereof by the aforementioned conveyor **205**.

In the upper part of the second module **250** a path for an air flow F**3** is realized comprising two branches, a heating branch **258** and a cooling branch **259**.

This path leads, above the conveyor **205**, into the bell **270**, below which the aforementioned HEPA filter **260** is fixed.

Inside the heating branch **258** a heating element **251** is arranged, which may be defined by a coil resistor and is intended for heating the air flow up to the aforementioned preset sterilising and depyrogenating temperature of the bottles **2**.

In the second module **250** a generating device **255** for generating the aforementioned air flow F**3** is also provided.

The generating device **255** comprises an inlet fan **256** arranged at an air intake **253** and suitable for sucking in air from the external environment, and a main fan **257**, arranged above the aforementioned hood **270**.

A refrigerating arrangement **265** is further present that is selectively activatable and is intended for rapidly cooling the air flow F**3** entering the second module **210**, when the latter is arranged in the cooling operating mode.

At the inlet of the aforementioned heating **258** and cooling **259** branches flow-commuting members **261** are provided.

These substantially comprise a pair of butterfly switches **262**, **263** commutable in push-pull mode as already disclosed previously.

In the upper part of the second module **250** an evacuation fan **264** is provided that is intended for conveying part of the circulating air flow to the external environment.

With this fan **264** a corresponding mixing valve **265***a* is associated that is arrangeable according to different opening degrees to lower the temperature of the exiting air.

By way of example, the operation of the sterilising and depyrogenating unit **200** for sterilising/depyrogenating the bottles **2** according to a hot-cold sterilising mode is now disclosed (from which it is also possible to deduce the other already aforementioned operating modes of the unit **200**, i.e. hot-hot, cold-hot or cold-cold).

The first sterilising module **210** receives a batch of bottles **2**, already suitably washed and decontaminated, from the loading inlet **201** on the conveyor **205**.

The butterfly commutator **222** at the inlet of the heating branch **218** is taken to the open position whereas the commutator **223** at the inlet of the cooling **219** branch is taken to the closed position.

The refrigerating arrangement **225** is kept inactive and the fans **216**, **217** are activated to create the air flow F**2** to the bottles **2**.

The air is then progressively heated, consequently heating the bottles **2** until the bottles **2** are brought up to the desired sterilising and depyrogenating temperature.

The bottles **2** are kept at this temperature for a preset period, after which the bottles **2** are conveyed from the conveyor **205** to the second module **250**, which realizes cooling.

Simultaneously, a new batch of bottles **2** to be sterilised can be loaded into the first sterilising stage **210** through the loading inlet **201**.

In the aforementioned second module **250** the butterfly commutator **262** is kept closed, whereas the commutator **263**, that inserts the cooling branch **259** into the air flow path, is kept open.

The inlet **256** and main **257** fans are then activated, as well as the refrigerating arrangement **265**.

The bottles **2** are then affected by a laminar flow of cold air and are brought up to a temperature that is compatible with the subsequent packaging operations.

The bottles **2** are then conveyed by the conveyor **205** to the unloading outlet **202** and then to a subsequent filling step of the bottles **2** with liquid or powder material.

The two-stage structure of the sterilising unit **200** as disclosed above enables several advantages to be obtained.

First of all, the possibility of having significant flexibility of use in function of different production needs. Further, the identical configuration of the two modules/stages with the possibility for both to carry out sterilising cycles, enables the internal environments of the two modules to be kept sterile always and in all cases.

In fact, performing a sterilising cycle on the bottles also automatically makes the operating environments sterile.

This constitutes a significant advantage compared with known sterilising devices which have to provide different and independent means for carrying out periodic sterilising cycles in the cooling section of the containers.

A further advantage is due to the fact that for the same production volumes the sterilising modules can be realized with smaller dimensions. The construction of a larger number of identical modules that therefore use identical components furthermore enables significant savings in production costs to be made.

It is understood that everything disclosed above has been disclosed purely by way of non-limitative example.

Possible modifications to and variations on the invention are therefore considered to fall within the extent of the protection accorded to this technical solution as disclosed above and claimed below.

The invention claimed is;

**1**. Unit for sterilising and depyrogenating containers of the type comprising a conveying device suitable for receiving a plurality of said containers through at least an inlet and supplying said containers in a set direction to a corresponding outlet of the unit wherein said unit comprises a sterilising/depyrogenating arrangement defined by at least two sterilising modules, arranged consecutively in said direction and communicating through an intermediate passage, and affected by said conveying device; said sterilising modules being activatable independently of one another according to alternative operating modes for hot sterilising and/or cooling said containers,

wherein each of said at least two sterilising modules comprises:

a generating device for generating an air flow, suitable for generating and conveying said air flow along a path to said containers;

a filtering element suitable for filtering said air flow up to a preset degree of purity;

a heating element suitable for heating said air flow and intended for affecting said containers inside a sterilising chamber to take said containers to a preset sterilising and depyrogenating temperature, along a heating branch affected by said heating element;

a refrigerating arrangement suitable for cooling said air flow along a cooling branch affected by said refrigerating arrangement;

a flow commuting member, arranged along said heating branch and a further flow commuting member arranged along said cooling branch;

said flow commuting member and said further flow commuting member being commutable between respective open and closed positions to connect or disconnect said heating branch or said cooling branch from said air flow path such that each of said at least two sterilising modules is selectively and alternatively operatable as a hot steriliser and in a cooling operating mode.

**2**. Unit according to claim **1**, wherein said sterilising/depyrogenating arrangement is completely enclosed inside a single insulated covering structure.

**3**. Unit according to claim **1**, wherein said two sterilising modules are substantially identical to each other; said inlet being provided in a first of said sterilising modules in relation to said direction and said outlet being provided in the second of said sterilising modules; said inlet and outlet being provided with relative corresponding shutters suitable for enabling the opening and closing thereof at the passage of said containers respectively entering and exiting said unit above said conveying device.

**4**. Unit according to claim **1**, wherein said flow-commuting member and said further flow commuting member comprise respective butterfly commutators commutable in push-pull mode between respective open and closed positions.

**5**. Unit according to claim **1**, wherein each of said sterilising modules comprises an evacuation fan suitable for conveying part of said air flow to the external environment; a corresponding mixing valve being associated with said evacuation fan.

**6**. Unit according to claim **1**, wherein the unit is configured to operate in the following alternative operating modes:

hot-cold, wherein the first module operates in the hot sterilising mode and the second module operates in the cooling operating mode;

hot-hot, wherein both of the modules operate in the hot sterilising mode;

cold-cold, wherein both of the modules operate in the cooling operating mode; and

cold-hot, wherein the first module operates in the cooling operating mode and the second module operates in the hot sterilising mode.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

# CERTIFICATE OF CORRECTION



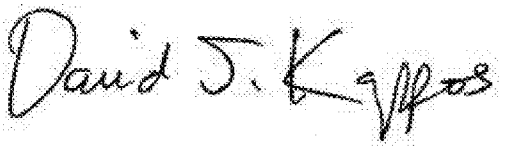
PATENT NO. : 7,811,533 B2
APPLICATION NO. : 11/794656
DATED : October 12, 2010
INVENTOR(S) : Claudio Bechini

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, Item (73) should read

-- (73) Assignee: IMA LIFE S.R.L.
Ozzano Dell'Emilia (BO) (IT) --.

Signed and Sealed this
Fifteenth Day of November, 2011



David J. Kappos
*Director of the United States Patent and Trademark Office*